

this place from the inside, in the way that those of us who serve here do.

The press and media people pack the gallery upstairs during a debate on a pay raise, but they rarely write or speak about the personal ramifications of the job here. This is not to complain. Every Member here feels that it is a supreme honor to serve as a Member.

But it is important that the public know more about what kinds of people serve here, how hard they work, the personal toll that is taken on individuals and families.

I have seen grown men here cry when their marriages were destroyed. I have seen grown men depressed about missing events that were important to their children.

In sports they have a term called "playing hurt," when players participate even when injured. Well, I have seen Members of the House "play hurt." Members who were ill and dragged themselves to the airport to keep an important commitment back home.

I have seen Members with serious illness or disease struggle to do a good job, to make rollcall votes and committee meetings.

The picture of the Congress presented to the public via the Abscam scandal was not a fair one. This is not a place where you can reach in and pick any seven Members and expect that they will accept money in a brown paper bag. It is not that kind of place and it is an insult to all who have served well here that such a picture of the Congress be presented.

Scandal is what sells newspapers and soap on the evening news. Pay raises and debates over them in this body are in the same category. But these things do not begin to tell the story of what happens here on a day-to-day basis.

What happens here on a day-to-day basis is a struggle to get things done, to do the right thing for our districts, for the Nation and the world. What gets in the way of that is familiar to all of us.

The hectic schedule is a problem. The lack of predictability in the scheduling. The tug and pull of various people and interests wanting our attention. The seemingly constant attention to getting reelected. The accompanying preoccupation with raising money. And, of course, the impact that such a preoccupation has on policymaking.

There must be a movement developed to deal with these problems. I believe we should move to a 4-year term with a limit of three terms in the House and two 2-year terms in the Senate. I believe we should move to a 2-year budget and plug in a requirement that the Congress do meaningful oversight for 3 or 4 straight months each year.

Most importantly, we need campaign reform—a limit on PAC's, public financing, free access to media, and many other important changes. The

political system is being contaminated by money and we must do something about it.

Such dramatic changes must take place with pressure from the outside and I intend to do my share as a private citizen in that regard.

Being a private citizen again will not be altogether unhealthy. Getting out of politics for a time will give me an important perspective.

But there will never be anything to take the place of the warm friendships I have developed here. I have not had the chance to thank each of my colleagues and staff for their kindness. I hope this statement will at least partially serve that purpose. \*

#### WHITE-FROEB STUDY DISCREDITED BY SCIENTISTS

HON. L. H. FOUNTAIN

OF NORTH CAROLINA

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 16, 1982

Mr. FOUNTAIN. Mr. Speaker, after 30 years of service to the people of the Second District of North Carolina, I am about to retire from the U.S. House of Representatives. Before leaving I would like to submit, for the Record, an item dealing with an issue with which I and many others have long been interested, namely, the alleged effect of smoking on the health of the nonsmoker.

Mr. Speaker, let me briefly place the issue into its proper context. In 1978, the Subcommittee on Tobacco of the House Committee on Agriculture heard testimony from a vast array of eminent scientists and physicians on the issue of the effect of tobacco smoke on nonsmokers. Those individuals who testified generally agreed that no conclusive scientific evidence exists to support the claim that smoking affects the health of nonsmokers. In 1980, however, an article appeared in the New England Journal of Medicine by Drs. White and Froeb entitled "Small Airways Dysfunction in Nonsmokers Chronically Exposed to Tobacco Smoke," in which the authors concluded that smoking in the workplace adversely affects the lung function of nonsmokers. This conclusion appeared to conflict with the testimony presented to the Subcommittee on Tobacco.

Since its publication, the White-Froeb study has been used to support both regulatory and legislative activities in the United States. For example, the study was referred to in testimony before the Civil Aeronautics Board during its recent consideration of rules regarding smoking aboard commercial aircraft. The National Research Council report entitled "Indoor Pollutants" which was issued in 1981 under an EPA contract also relies on the study. Finally, the White-Froeb study has received widespread attention in both State and local legislative and policymaking bodies.

The White-Froeb study continues to play an important role in legislative considerations, despite the fact that the study itself has been heavily criticized by scientists and health practitioners. Most recently, at the 1982 joint meeting of the American Lung Association-American Thoracic Society, Dr. Michael D. Lebowitz, professor of internal medicine, college of medicine, University of Arizona and special consultant to the Subcommittee on Tobacco, presented reasons why, in his own words, "the results of this study cannot be used to demonstrate an effect of passive smoking on forced expiratory flows in adults exposed in the workplace." Dr. Lebowitz, a noted specialist in epidemiology and respiratory diseases, said that the basic problem with the White-Froeb study is that it is "improperly designed" and that "there are problems with the whole data set and with the conclusion." Dr. Lebowitz also expressed concern that the significance of the White-Froeb data appeared to depend upon their unexplained omission of data from 3,000 subjects originally included in the study.

Mr. Speaker, Dr. Lebowitz wrote a letter, dated July 10, 1981, to our colleague, Congressman Charles Ross, Chairman of the Tobacco and Peanut Subcommittee of the House Agriculture Committee, as a result of a personal interview which Chairman Ross and Dr. Lebowitz had with Dr. White. With the personal consent of Chairman Ross, I am inserting herewith Dr. Lebowitz's letter. It more fully explains the author's views regarding the White-Froeb study.

I also want to mention another evaluation of the White-Froeb study, one which was made by Dr. J. G. Gostomzyk, director of the department of health of the city of Augsburg, West Germany. After an extensive, detailed review of the White-Froeb study, Dr. Gostomzyk has concluded that the White-Froeb data were incompletely presented and did not satisfy the prerequisites for scientific credibility. In addition, Dr. Gostomzyk remarked that "Dr. White's methodology is not scientific but that of a lay person with convictions," and concluded that "we assume that Dr. White's study is an attempt at scientific validation of his credo and that he possibly is unaware of the inadequacy of this methodology." It is obvious that Dr. Gostomzyk is referring to Dr. White's outspoken antismoking activities in California, including Dr. White's endorsement of public smoking referendums which were, incidentally, twice rejected by the California voters.

Given these and other criticisms of the White-Froeb study, it would appear that the New England Journal of Medicine has, perhaps unwittingly, performed a disservice to its readership. It is extremely unfortunate that a study so fraught with methodological problems, as indicated through

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numerous criticisms by scientists in the United States and elsewhere, should have been published in such a reputable journal of medicine. The White-Froeb study should, therefore, not be relied upon by the Congress, Federal agencies, or other legislative or policymaking bodies when considering restrictions on smoking in public places.

THE UNIVERSITY OF ARIZONA,  
COLLEGE OF MEDICINE,  
Tucson, Ariz., July 18, 1981  
Congressman CHARLES ROSE,  
Chairman, Subcommittee on Tobacco and  
Peanuts, House of Representatives, Ray-  
burn Building, Washington, D.C.

DEAR CONGRESSMAN ROSE: The following is a summary of my notes on our visit to Dr. James White at UC San Diego, as per our discussion. Unfortunately, despite the statement in the editorial of the New England Journal of Medicine (27 March 1980), Dr. White and his co-author did not "faultlessly demonstrate a reduction in measures of small airways of healthy non-smokers exposed to cigarette smoke in the work place". It is apparent from our visit and the article that there were various faults in the present study, which shall be discussed.

The problems with the research design are as follows:

The participants were not only volunteers, but generally had to pay for the physical fitness course; this is the reason most were white-collar. Employees in specific factories invited White to run the physical fitness course in their factories as well, which would also bias the population sample. Blue-collar workers were not distributed randomly. (It has to be assumed that volunteers in the physical fitness courses fall into unrepresentative categories: the highly motivated, with an interest in health and usually healthier, those who are worried about health and generally less healthy; the first group would include fewer smokers and the second group would include more smokers.)

The questionnaire utilized was not a validated one per se; test-retest comparisons were made only on the smoking questions and very small groups of subjects. The smoking information was not validated. There were no test-retest or validations on symptoms asked in the questionnaire. The questionnaire itself was derived by the investigator, and included some questions from standard questionnaires, this did not appear to include standard respiratory questions, and in fact various typical respiratory questions (such as phlegm) were not asked. The questionnaire did not include questions on altitude, but did include questions on activity levels and jobs (duration, type). The questionnaire did ask how many smokers were in their work area, room size, and nature of the air conditioning. It also included questions about residences in the last 20 years (zip codes), so that exposures away from work were assessed by residential location. A question was asked about smokers in the home. (Thus, the smoking information is not validated, but is probably relatively accurate. The information about exposure to passive smoking is only approximate, as is the information on other occupational exposures. Exposures to air pollutants or to unknown toxic gases in the working place is only approximate, and their effects underestimated.)

Dr. White presented a paper to the American College of Sports Medicine, the abstract for which in 1977 indicated there were 7,122 subjects enrolled between 1969 and 1977. However, in the New England Journal of Medicine article, he states that the base

population analyzed is only 5,210 smokers and non-smokers enrolled between 1969 and 1979. Although he excluded all the ex-smokers, some whose zip codes were missing, his answers as to why the rest of the subjects were excluded were entirely unclear and tend to indicate potential bias in selection of subjects for consideration for analyses. It might be added that the 2,100 subjects analyzed in the NEJM article and those analyzed and presented in the Sports Medicine abstract appear to be the same as they yield exactly the same table of results (as determined from comparison of the table in the Sports Medicine manuscript and the NEJM table).

In addition to the sources of bias mentioned above, it is apparent that the non-smokers in clean work environments and those in smoking work environments have not only chosen not to smoke, but it is likely that those non-smokers working in smoking environments may be different for a variety of reasons from non-smokers working in clean environments. Furthermore, it is apparent that the non-smokers in non-smoking environments are quite different in that their lung function is "super normal" in comparison even with the Seventh Day Adventists (the source of the Morris prediction equations).

Dr. White did state that from the questionnaire and from the baseline tests that there were no significant differences in the three non-smoking/non-inhaling groups in terms of the amount of previous exercise or oxygen consumption, but he was unsure of the difference in percent of body fat. Smokers did have less body fat, were less in terms of having lower oxygen consumption, and had less activity. He says further that there were no differences between the groups in terms of childhood respiratory history (lower respiratory tract illnesses) from his submitted questionnaire information, but he did not ask about family history. He did not ask sufficiently about respiratory questionnaires to appropriately exclude groups on the bases of productive cough ("cough bronchitis"). He states that there were no differences in prevalence rates of questionnaire responses by zip codes; if so, this contradicts other evidence *vis-a-vis* the effects of air pollution in these areas. He was not able to assess other exposures such as those from hobbies, exposures to gas stoves, or transportation. In terms of passive smoking in the home, he excluded such passive smokers from the non-smoking and passive smoking groups, but not from any smoking groups. He was not able to provide any information about the distribution of characteristics in those eliminated from the original 7,000 or the 2,208 that qualified because of other questionnaire results.

With regards to the pulmonary function testing done by Dr. White, it must be first noted that the instrument used is not considered a satisfactory instrument in that it is non-linear (highly biased) at both high volumes and low volumes. (This has the effect of maximizing differences in that anyone with minor aberrations of total vital capacity or of flows at the end of the flow volume curve would have very different, that is, low, flows.) The comparisons that Dr. White did and reported on in his response letter in the NEJM (14 August 1980) would not in any way modify this opinion. Furthermore, Dr. White has the only pulmonary function technician and reader. Even though he was trained at the VA hospital and his techniques were evaluated by test-retest and by comparison to other readers, any biases inherent in Dr. White's thinking (see below) would affect the way he read the tests. Furthermore, he took the FEV<sub>1</sub> and flows off the same spirogram

using an approximation technique published by Morris et al., which is not an adequate or accurate representation of those measures. All of his tests were baseline tests done after two and a half hours in the classroom in the evening on those without acute respiratory illnesses (usually on a Monday or Tuesday evening); thus, there is probably little diurnal variation or pretest biases other than those experienced by the workers during their work day and in their activities prior to the classroom. Although it is difficult to judge the effects of these factors, they may have influenced the test results, especially in those with any significant exposures during the day.

The major problem with the pulmonary function test results as reported is that they are not age- and height-adjusted; since lung volumes and flow rates are associated with both of these factors. In other words, Dr. White used raw values of flows and volumes to do comparisons. He did this on the assumption that the mean age and height were similar for the different groups. This is a mistake, since the distributions for those ages and heights could have differed. Furthermore, his quoted figures for percent predicted are strictly for the average person, age 49, with an average height, and does not represent the group for which they are provided. In terms of these statistical analysis, he just chose the SNK package among many. There is no correlation coefficient per se. "Normality" was not an objective of this study, so he cannot state anything about the normality of the subjects studied, including those he considered to have significantly different results from the non-exposed non-smokers. He does not understand the difference between clinical meaningfulness and statistical significance. It is quite obvious that the majority of those in the passive smoking and in the non-inhaling group are quite normal and that very few would be considered abnormal by any criteria.

In his reported results, he quotes as incorrect significance level of  $p < .005$ , whereas the level provided by the technique is  $p < .05$ . This is very different, given the number of comparisons made, and indicates that some of the results would not be significant if corrections were made for the number of comparisons. Furthermore, the data presented in Table 1 was used to recompute the SNK analysis by Mary C. Townsend, MPH (Department of Epidemiology, University of Pittsburgh). Those results differ from those published by Dr. White and are provided in the attachment. The most important of the differences is the finding that the passive smokers and light smokers differ for the male FEV<sub>1</sub> 75-85 percent. Thus, the effect of passive smoking on non-smokers is still unconfirmed, despite Dr. White's unfailing conviction that it is confirmed.

Other minor points: In terms of the carbon monoxide sampling, although it is stated that it was randomized, it was really on only 40 smoking and 40 non-smoking situations chosen by chance but not by random selection. Dr. Froeb, the co-author with Dr. White, is a private practitioner in La Jolla and helped Dr. White in drafting the NEJM manuscript from the manuscript presented at the American College of Sports Medicine. It might be pointed out that San Diego is not strictly low in air pollution concentrations, nor uniform throughout the area; this may bias some results. Dr. White performed the pulmonary function tests until "reproducible curves were obtained", but they do not necessarily follow the International, Snowbird, or ATS recommendations.

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In reviewing Dr. White's response to the letter to the Editor in the NEJM (14 August 1980), it is quite clear that Dr. White did not satisfactorily answer all the questions raised, many of which are similar to those raised in this letter. It is questionable, from the discussion, whether Dr. White would pursue any further re-analysis of the data, nor necessarily could it be pursued. It is questionable, given the basic underlying problems in the research design, that re-analysis of the data would be worthwhile. On the other hand, given other results that contradict Dr. White's, including those now in press (such as Comstock et al., Johns Hopkins, presented at the Society for Epidemiological Research in June of 1981), it would be likely that a panel discussion of passive smoking might be valuable. I will be glad to furnish further discussion or help in that matter.

Sincerely,

MICHAEL D. LEDOWITZ, Ph.D.  
F.C.C.P.  
Professor of Internal Medicine

TOM BUTTERFIELD

HON. IKE SKELTON

OF MISSOURI

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 16, 1982

● Mr. SKELTON. Mr. Speaker, as 1982 draws to a close, it is customary to reflect upon the events of the past year. I would like to talk about an experience I had just over a year ago and about some sad news I heard just this week.

In December of 1981, a movie called, "The Children Nobody Wanted" was televised. This moving story depicted the work of a man named Tom Butterfield and the help he gave to fosterlings in Marshall, Mo. On Monday, December 13, my longtime friend, Tom Butterfield died of respiratory failure.

"The Children Nobody Wanted" is a true story. When Tom Butterfield was a freshman at Missouri Valley College in Marshall, Mo., he discovered the problems of children who have nowhere to go, and for whom the law makes few, if any, provisions. Boy by boy, he made a life for these homeless youngsters. Tom fought increasing odds, from the lack of money, to outdated laws. He became the youngest single adult—and the first bachelor—to be a legal foster parent in the State of Missouri. He and his boys rented an old country club and turned it into their ranch. Today, there are four ranches, giving a homelife to over 100 youngsters.

During this special time of the year, it is good to stop and think about the road we are traveling. Looking at the trail of Tom Butterfield's life, I can see that, although he died at the young age of 42, his contributions will go on for a very long time to come. It is appropriate, at this time of gift-giving, to look back at all the giving this man has done in his lifetime.●

# ADMINISTRATION'S INSENSITIVE APPROACH TO CANCER

HON. ALBERT CORE, JR.

OF TENNESSEE

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 16, 1982

● Mr. GORE. Mr. Speaker, the present administration appears to be headed down a regulatory path that will needlessly expose millions of people to many known, cancer-causing chemicals at levels well beyond those traditionally accepted as safe and prudent. One example, documented in hearings held before the Investigations and Oversight Subcommittee of the Committee on Science and Technology which I chaired, was EPA's failure to take rapid action in setting reasonable limits for exposure to formaldehyde, although it is unquestionably an animal carcinogen. My colleague, Hon. George E. Brown, Jr. has done some excellent work in this area and has found similar evidence of EPA's failure to regulate certain pesticides that have been clearly shown to cause tumors in animals. Two recent articles in the New York Times (Dec. 4, 1982) and the Baltimore Sun (Dec. 8, 1982) provide further documentation of the new, high-risk approach to Federal cancer policy. I commend them to the attention of my colleagues. It is time for us to halt this administration's crass and insensitive bottom-line approach in which costs to industry are balanced against increased human suffering. We all owe a debt of gratitude to the gentleman from California and I am looking forward to his forthcoming subcommittee report on this subject.

The articles follow:

[From the Baltimore Sun, Dec. 8, 1982]

## EPA AND CANCER: THE SLEEPING STANDARDS (By Ken Cook)

WASHINGTON.—In what some critics charge is a fundamental and unjustified change in federal cancer policy, the Environmental Protection Agency (EPA) has determined that an insecticide which caused cancer in laboratory animals poses no cancer risk to human beings.

The decision removes the last barrier to the permanent registration of the insecticide permethrin for use on dozens of U.S. crops.

As a result of emergency exemptions granted by the agency since 1977, permethrin already is one of the country's major insecticides, used on millions of acres of vegetables, beans and cotton each year. Permethrin is marketed under the trade names Pounce and Ambush.

A leading critic of the EPA decision, Representative George E. Brown, Jr. (D., Calif.) characterizes the permethrin ruling as "one of several actions that suggest the EPA has adopted a new set of scientific principles in reaching regulatory decisions on proven animal carcinogens."

Federal pesticide law does not prohibit registration of cancer-causing chemicals if dietary and occupational exposure can be kept below the safety level established by the agency. By contrast, the Food and Drug Administration must by law prohibit the use

of any food additive shown to cause cancer in laboratory animals.

The practical effect of a decision to brand permethrin as a human carcinogen would have been a greater restriction on the number of crops for which it could be registered. Such a ruling might also have left the manufacturers, FMC Incorporated of Philadelphia, and ICI, a British firm, more vulnerable to product liability suits.

John W. Melone, director of EPA's hazard evaluation division and author of the permethrin decision (which appeared in the *Federal Register* in October), said that one of the long-term animal studies submitted by a manufacturer in support of the chemical's registration, "was clearly positive" for cancer. It reported that tumors had appeared on mice after they had been fed permethrin over an extended period. Mr. Melone said five other studies submitted by manufacturers were accepted by EPA as showing no cancer-causing effects in laboratory animals. However, Mr. Melone described one of those studies as "quite controversial" because EPA scientists could not agree on the results. A seventh study, also conducted by a manufacturer, was rejected because of irregularities in the way it was conducted.

Mr. Melone described the permethrin case as "unique" for having so many long-term studies available for scrutiny by EPA scientists. Only two such studies normally are required for pesticide registration.

"We concluded that the weight of evidence suggested this chemical is highly unlikely to be a potential human oncogen (tumor-inducing substance)," Mr. Melone said in a telephone interview. "And since we have to make a decision, we believe permethrin should not be regulated as a potential human oncogen."

Regarding the permethrin ruling, Mr. Melone said, "There's no question it's a change in perspective."

Representative Brown, chairman of the House Subcommittee on (Agriculture) Department Operations, Research and Foreign Agriculture, which has jurisdiction over EPA's pesticide program, said that "for the agency to adopt a policy which, in effect, attempts to balance positive tests with negative ones is clearly a bold step."

Mr. Brown considers the action "a monumental and quasi-scientific leap of regulatory faith."

There is a continuing debate among cancer experts over how to weigh various types of evidence to determine a chemical's potential to cause cancer in humans. Although the precise mechanisms of cancer remain unknown, scientists have for some time agreed that proven animal carcinogens do not all pose an equal risk of cancer to humans. Traditionally, cancer regulatory decisions, including those made by EPA, have been made as if they did.

In the past few years, several cancer researchers and research institutions have proposed detailed systems by which regulatory agencies might distinguish between "strong" and "weak" carcinogens, based on information gained from long-term animal studies such as those submitted in the permethrin case. Regulatory actions might then take the form of an outright ban if such a system ranked the chemical as a strong cancer risk. Chemicals judged to be weak would be regulated less stringently, or not at all.

Last summer, EPA circulated to a select group of experts a draft of a proposal to modify the agency's original cancer policy guidelines promulgated in 1976. The draft proposed a ranking system similar to one developed by the International Agency for Re-

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